

**AXELOFEIN- minoxidil 2% solution/ drops**  
**TRILOGIC, LTD**

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**AZELOFEIN HAIR GROWTH SOLUTION**  
**2% MINOXIDIL TOPICAL SOLUTION**

Minoxidil 2% w/v

**USE**

Use to regrow hair on the scalp

Hair regrowth treatment

For external use only.

Flammable: Keep away from fire or flame.

Do not use if:

- Your degree of hair loss is different than shown on the side of this carton, because this product may not work for you
- You have no family history of hair loss
- Your hair loss is sudden and/or patchy
- Your hair loss is associated with childbirth
- You do not know the reason for your hair loss
- You are under 18 years of age. Do not use on babies or children
- Your scalp is red, inflamed, infected, irritated, or painful
- You use other medicines on the scalp

Ask a doctor before use if you have heart disease

**WHEN USING THIS PRODUCT**

- Do not apply on other parts of the body
- Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water
- Some people have experienced changes in hair color and/or texture
- It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results
- The amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if

- Chest pain, rapid heart beat, faintness, or dizziness occurs
- Sudden, unexplained weight gain occurs
- Your hands or feet swell
- Scalp irritation or redness occurs
- You get unwanted facial hair growth
- You do not see hair regrowth in 4 months

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- apply one mL with dropper 2 times a day directly onto the scalp in the hair loss area

- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

OTHER INFORMATION

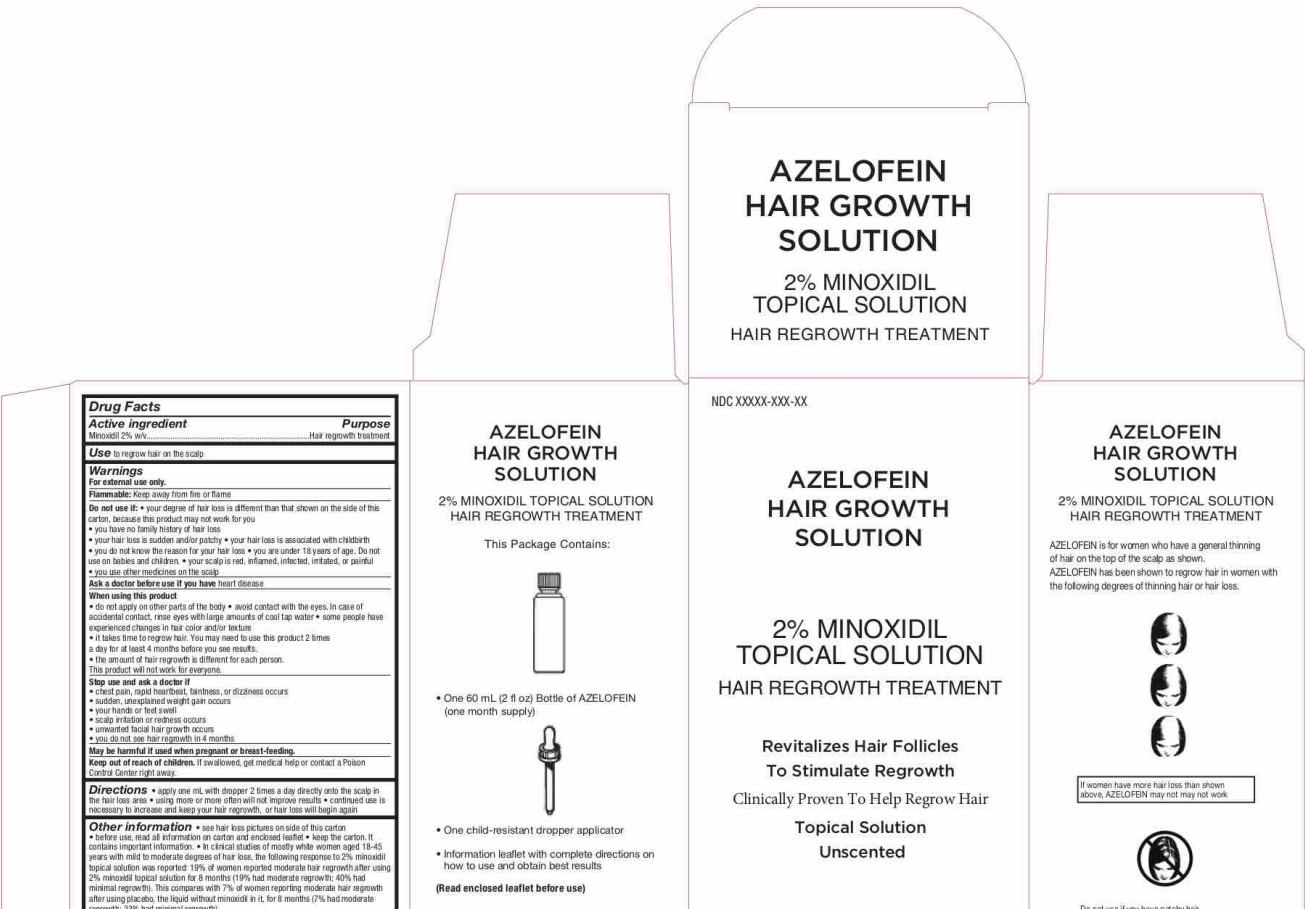
- See hair loss pictures on the side of this carton
- Before use, read all information on carton and enclosed leaflet
- Keep the carton. It contains important information
- In clinical studies of mostly white women aged 18-45 years with moderate degrees of hair loss, the following responses to 2% minoxidil topical solution was reported: 19% of women reported moderate hair regrowth after using 2% minoxidil topical solution for 8 months (19% had moderate regrowth; 40% had minimal hair regrowth). This compares with the 7% of women reporting moderate hair regrowth after using a placebo, the liquid without minoxidil in it, for 8 months (7% had moderate regrowth; 33% had minimal regrowth).
- Store at controlled room temperature 20 o to 25 oC (68 o to 77 oF)

Alcohol, Propylene Glycol, Purified Water

Questions or comments? +7-499-753-04-34

- Visit Website at [www.simone.su](http://www.simone.su)

Alcohol, Propylene Glycol, Purified Water



• store at USP controlled room temperature 20° to 25°C (68° to 77°F)  
**Inactive ingredients:** Alcohol, Propylene Glycol, Purified Water  
**Questions or comments?** +7-499-753-04-34  
• Visit Website at [www.demine.ru](http://www.demine.ru)

Made in USA  
Distributed By: OOO  
TRILOGIC LTD.  
Krizhanovskogo st.14/3  
117218 MOSCOW-RUSSIA

One Month Supply  
One 60mL (2 fl oz) Bottle

Any loss will be in your return packaging only  
loss as shown above.



Lot No.

Expiration

Label Part#

Rev. Date

<p>NDC#</p> <p><b>AZELOFEIN</b></p> <p><b>2% Minoxidil Topical Solution</b> <b>Hair Regrowth Treatment</b></p> <p>UNSCENTED</p> <p>CLINICALLY PROVEN TO HELP GROW HAIR</p> <p>REVITALIZES HAIR FOLLICLES</p> <p>TOPICAL SOLUTION</p> <p>One Month Supply 60 mL (2 fl oz)</p>	<p>Read and keep carton and leaflet for full product information</p> <p>Active ingredient Minoxidil 2% w/v</p> <p><b>Warnings</b></p> <p><b>For external use only.</b></p> <p><b>Flammable:</b> Keep away from fire or flame</p> <p><b>Do not use if</b></p> <ul style="list-style-type: none"><li>• you have no family history of hair loss</li><li>• your hair loss is sudden and/or patchy</li><li>• your hair loss is associated with childbirth</li><li>• you do not know the reason for your hair loss</li><li>• you are under 18 years of age. Do not use on babies and children.</li><li>• your scalp is red, inflamed, infected, irritated, or painful</li><li>• you use other medicines on the scalp</li></ul> <p><b>Ask a doctor before use if you have heart disease</b></p> <p><b>When using this product</b></p> <ul style="list-style-type: none"><li>• do not apply on other parts of the body</li><li>• avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.</li><li>• some people have experienced changes in hair color and/or texture</li></ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"><li>• chest pain, rapid heartbeat, faintness, or dizziness occurs</li><li>• sudden, unexplained weight gain occurs</li><li>• your hands or feet swell</li><li>• scalp irritation or redness occurs</li><li>• unwanted facial hair growth occurs</li></ul>	<p>May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• apply one mL 2 times a day directly onto the scalp in the hair loss area</li><li>• <b>see inner carton and enclosed leaflet for complete directions</b></li><li>• using more or more often will not improve results</li><li>• continued use is necessary or hair loss will begin again</li></ul> <p><b>Inactive ingredients</b> alcohol, propylene glycol, purified water</p> <p><b>Questions?</b> Call (OOO TRILOGIC LTD. +7 (499) 753-04-34) or reach us on the internet at <a href="http://www.simone.su">www.simone.su</a></p> <p><b>Store at Controlled Room Temperature 20° to 25°C (68° to 77°F)</b></p> <table><tr><td>LOT#</td><td>Label part#</td></tr><tr><td>EXP</td><td>Rev. date</td></tr></table> <p>Dist by: TRILOGIC LTD Address: Krizhanovskogo street 14 str. 3, 117218, MOSCOW, RUSSIA</p>	LOT#	Label part#	EXP	Rev. date
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EXP	Rev. date					

minoxidil 2% solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73237-001
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MINOXIDIL (UNII: 5965120SH1) (MINOXIDIL - UNII:5965120SH1)	MINOXIDIL	2 g in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73237-001-01	1 in 1 BOX	07/10/2019	
1		60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA078176	07/10/2019	

**Labeler** - TRILOGIC, LTD (682372062)

Revised: 7/2019

TRILOGIC, LTD